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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,538	08/18/2005	Gilbert Jay	Origen-0036	4835
23599 7590 10/05/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER QIAN, CELINE X	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/511,538

**Applicant(s)**

JAY ET AL.

**Examiner**

Celine X. Qian Ph.D.

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 172-190 and 198-200 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 172-190 and 198-200 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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### **DETAILED ACTION**

Claims 172-190, 199 and 200 are pending in the application.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 172, 173, drawn to a method of detecting a pancreas cell by contacting a sample comprising cells with a polynucleotide hybridizes to one or more of the recited gene.

Group II, claim(s) 174, 175, 181-183, 189 and 190, drawn to a method of detecting a pancreas cell by contacting a sample comprising cells with a binding partner for a polypeptide coded by the recited gene.

Group III, claims 176-179, drawn to a method of delivering an agent to a pancreatic cell by contacting a pancreas with an agent coupled to the binding partner specific for the recited gene.

Group IV, claims 180, 187, 188, drawn to a method of modulating a pancreas, immune or reticuloendothelial cell by contacting a cell with an agent that modulates the recited gene.

Group V, claims 184, drawn to a method of expressing a heterologous polynucleotide in pancreas cell by expressing a nucleic acid construct in pancreas cell, wherein the nucleic acid is under the control of a promoter selected from the recited sequence identifier (SEQ ID NO:258-344)

Group VI, claim 185, 186, drawn to a method of assessing a therapeutic or preventive intervention in a subject having a pancreas or lymphoid disease by determining the expression level of the recited gene.

Group VII, claims 198, drawn to a method of selecting a gene predominantly expressed in pancreas tissue by using a computer database.

Group VIII, claim 199, drawn to a composition comprising gene or polypeptide which are expressed predominantly in pancreas tissue comprising the recited gene.

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Group IX, claim 200, drawn to a method of treating pancreas cancer by administering an antibody specific for TMD0645.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature.

The special technical feature of Group I is nucleic acid that hybridizable to the recited genes, which is not shared by the rest of the groups. The special technical feature of Group II is binding partners of recited genes, which is not shared by the rest of the groups. The special technical feature of Group III is binding partners of the recited genes coupled to an agent that is delivered to the pancreas, which is not shared by the rest of the groups. The special technical feature of Group IV, a modulating agent that modulates pancreas, immune or reticuloendothelial cell, which is not shared by the rest of the groups. The special technical feature of Group V is a construct for expressing a polynucleotide under the promoter represented by SEQ ID NO:258-344, which is not shared by the rest of the groups. The special technical feature of Group VI is determining the expression level of recited genes to assessing therapeutic or preventive intervention, which is not shared by the rest of the groups. The special technical feature of Group VII is a retrievable database comprising sequence information of the recited gene, which is not shared by the rest of the groups. The special technical feature of Group VIII is a composition comprising nucleic acid of recited genes, and or polypeptide encoded by said genes, which is not shared by the rest of the groups. The special technical feature of Group IX is antibody to TMD0645 for treating pancreas cancer, which is not shared by the rest of the groups.

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Group V is comprised of multiple inventions which are the methods drawn to independent sequences which do not render obvious each other and thus are not united by a common special technical feature. If any of Group V is elected, applicants must elect a single invention which is the method drawn to one specific sequence to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Additionally, Groups I-IV and VI-VIII is subject to further restriction. Each group detailed above reads on patentably distinct genes. Each gene, or combination of genes, is patentably distinct because they are unrelated sequences that are not unified by a common special technical feature, and a further restriction is applied to each group. Applicant must further elect a single gene or a specific combination of genes. Please include in the election of sequence or specific combination of sequence the SEQ ID(s), the genebank numbers(s) (or any other identifier). This is NOT an election of species. Each molecule of a gene encodes a gene product which is chemically and structurally distinct from another product, such that they do not share a common unifying feature. As such, the method depending on one recited gene, or a combination of recited genes do not share a common unifying feature under PCT Rule 13.2.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

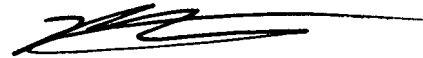
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Celine X Qian Ph.D.  
Examiner  
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CELINE QIAN, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', with a long horizontal stroke extending to the right.